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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,966	04/11/2005	Roberto Oliva	28427/GM/ps	3191
<div>7590 Modiano & Associati Via Meravigli, 16 Milano, 20123 ITALY</div>				
			<div>EXAMINER MATTER, KRISTEN CLARETTE</div>	
			<div>ART UNIT 3771</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 11/29/2007</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,966

Applicant(s)

OLIVA, ROBERTO

Examiner

Kristen C. Matter

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3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 14 is/are rejected.
- 7) ☒ Claim(s) 9-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

In the instant case, "1.56 (a)" should be changed to --1.56--.

Specification

The abstract of the disclosure is objected to because the abstract is one run-one sentence. In addition, the term "comprises" is considered claim language. Examiner suggests changing "comprises" to --includes--. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities:

The pages should be numbered in consecutive order (i.e., it appears the pages are numbered 1, 1bis, 2, 2bis, 3, 4, 5, 6, 7 and examiner is unsure what 1bis and 2bis represent);

On pages 1, 1bis, and 2, an entire paragraph appears to be bolded and the bold font should be removed;

On page 1bis, line 9, "covertor" should be changed to --cover to-- to correct the typographical mistake;

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On page 2, last line, "resent" should be changed to --present-- to correct the typographical mistake;

On page 2bis, the heading "Disclosure of Invention" should be changed to --Brief Description of the Drawings--; and

On page 3, line 12, the heading --Detailed Description of the Drawings-- should be added--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 recites the limitation "the guide tooth" in line 7. There is insufficient antecedent basis for this limitation in the claim. Examiner believes this is referring to the "guide spur".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Pera (US 7,025,059).

Pera discloses, in a single dose inhaling device, a main body having an inhalation conduit (12), wherein the main body has a first surface (located at 13a and extending to 13b in Figure 18) that extends planar and parallel to a longitudinal axis of the inhalation conduit and exhibits a hole (area between 13a and 13b) for communication with the inhalation conduit, the inhaler also comprising a second body (3H) which exhibits a second surface (located by 12a and 12b in Figure 18 where the cover 3H touches the first surface), shaped complimentary to the first surface and placed in contact with the first surface, on which first surface is fashioned a housing (6H) into which a capsule (4) can be at least partially inserted, the second body being rotatably coupled (column 20, lines 13-15), and being able to rotate from an open position in which the housing is accessible from outside for insertion of a capsule (see Figure 18) to a closed position in which the housing is aligned with the hole (the housing is always aligned with the hole), the inhaler also comprising a cutting means for cutting off a portion of the capsule upon rotation of the second body comprising a cutting edge (8H) arranged peripherally on the first surface (the blade is said to be peripheral because it lies near the outer edge of the first surface as opposed to in the center), a cut portion of the capsule remaining external of the inhaler (only the cut portion drops into reservoir 11).

Allowable Subject Matter

Claims 9-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and

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any intervening claims. In addition, claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record does not disclose an inhaler with the combination of structural limitations outlined in claim 1 in addition to the first surface comprising an apex and a perpendicular pivot at the apex with a guide surface arranged along an arched edge of the first surface having an undercut and a strike surface.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art cited is to show other single dose inhalers that cut capsules for delivering medicament.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen C. Matter
Examiner
Art Unit 3771



Danton D. DeMille
Primary Examiner